



LATTA.002C3

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Latta, Paul P.
Appl. No. : 10/660,924
Filed : September 12, 2003
For : PREVENTION OF DIABETES
THROUGH INDUCTION OF
IMMUNOLOGICAL
TOLERANCE
Examiner : Belyavski, Michail A.
Group Art Unit : 1644

SECOND DECLARATION OF DAVID SCHARP, M.D.
UNDER 37 C.F.R §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

1. I, David Scharp, M.D., am Chief Scientific Officer of Novocell, Inc. At Novocell I am actively engaged in research related to development of treatment of diabetes using encapsulated insulin-producing cells.
2. I have extensive experience in the field of the claimed invention as indicated in the attached Curriculum Vitae provided herewith as Exhibit A.
3. There are two potential animal models for studying Type I diabetes, the BB rat and the NOD mouse. The BB rat, while developing diabetes, has a multitude of immunologic disorders that makes it more of a model for immune deficiency than diabetes. The BB rat is no longer considered an acceptable model for studying human autoimmune diabetes.
4. The NOD mouse is therefore, the only animal model for human autoimmune, Type I diabetes in that it is predictive of human disease. Its lymphocytes spontaneously begin attacking

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its insulin-producing pancreatic beta cells soon after birth. Looking at the histology of the pancreas of these mice during the autoimmune process, one finds early that most islets are infiltrated with immune cells that are destroying islets. As the process continues towards the diabetic phase, almost all of the beta cells are destroyed leaving smaller than normal islets with residual inflammation that continues to destroy the new islets that are stimulated to develop due to the failing islet mass. This ongoing destruction of the insulin-producing pancreatic beta cells continues and progresses for 15 to 32 weeks until a sufficient number of beta cells are destroyed to cause the clinical onset of Type I diabetes in NOD mice. Examining living NOD mice prior to development of clinical diabetes, including monitoring their blood glucose levels, one would have no clue that this autoimmune process is actively destroying their pancreatic beta cells. Yet, if one examines their blood for anti-islet protein antibodies, one can clearly identify those animals that will eventually lose blood glucose control and develop clinical diabetes. This situation is identical for human Type I diabetes in that patients at high risk for developing Type I diabetes are tested for the presence of specific auto-antibodies. The number and titers of these specific antibodies can now predict with >90% certainty which of these patients with ongoing autoimmune destruction of their beta cells will actually develop clinical Type I diabetes within 5 years.

5. By following a large number of patients over time, it has been determined that there are clearly many years available in which to intervene in the auto-immune process prior to the development of clinical diabetes in an attempt to prevent it, if there were an effective prevention method available. Six drugs have been tried in patients with documented evidence of autoimmune diabetes to determine if human diabetes can be prevented. To date, such drug treatments have not been effective in preventing clinical diabetes in humans.

6. Our approach is totally different in that we are not giving drugs to prevent diabetes. Instead, we are implanting a very small fraction of encapsulated islet allografts into these NOD mice prior to the development of clinical diabetes in order to stop the onset of clinical, Type I diabetes. This fraction of encapsulated islets is so small it would have no effect on controlling blood glucose if given after diabetes had begun and therefore, is not a treatment for diabetes. We believe that the continuous release of donor antigens from the small fraction of encapsulated

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islets that are not destroyed by the host, alters the auto-immune response in a way that the host no longer considers the islets to be foreign. In this way, the immune attack on the islets within the pancreas stops prior to the onset of clinical diabetes and thus prevents clinical diabetes.

7. In my previous declaration, filed on April 1, 2004, I presented the data from the NOD mouse study on Prevention of Type I diabetes. This data has now been summarized into two bar graphs to allow an easier analysis.

8. Islets from mouse strain C57Bl/6 were encapsulated by polyethylene glycol conformal coating as described in USP 5,529,914. This patent was incorporated by reference into the specification of the application captioned above. The conformally-coated islets were implanted by intraperitoneal injection into NOD mice. The experiment had two variables under study – time of implantation of the encapsulated islets (4, 8, and 12 weeks) and number of islets implanted (50, 100 and 150 islet equivalents, IEQ).

9. Exhibit 1 shows the data for all animals grouped by time of implantation. Implantation at 4 weeks showed the best results with diabetes being prevented in 60% of the treated animals, as compared to the control animals with none having diabetes prevented.

10. Exhibit 2 shows the data for all animals grouped by number of islets implanted. A dose of 50 IEQ produced the best results with diabetes being prevented in 60% of the treated animals. All the control animals developed diabetes.

11. Exhibit 3 demonstrates that in the control recipients (NOD mice not implanted with encapsulated islet cells), the autoimmune destruction of the pancreatic islets is very complete with small shrunken islets remaining with continuing evidence of lymphocytes destroying any new islets that are formed.

12. Exhibits 4 & 5 demonstrate that in those recipients that were prevented from developing diabetes after implanting the small quantity of encapsulated islets, very large islets (many times their normal size) are present, without evidence of host lymphocyte destruction. This means that the normal process in the mouse to replace lost islets has been successful to the point of preventing diabetes from destroying all of the newly formed islet cells.

13. This demonstrates that the method of the present invention prevents type I diabetes.

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14. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or patent issuing therefrom.

Dated:

April 28, 2005

By:


David Scharp

1678364
042105



Prevention of Diabetes in NOD Mice with Implants of Encapsulated Islet Allografts

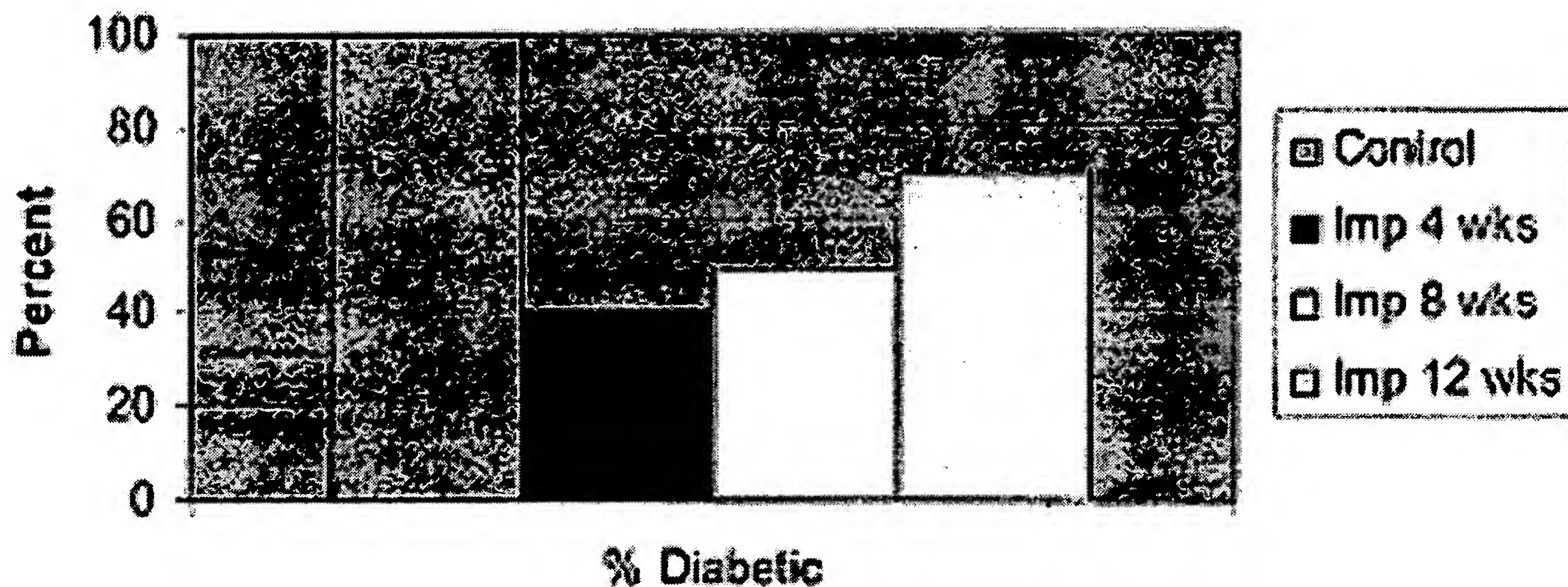


Exhibit 1

Prevention of Diabetes in NOD Mice with Implants of Encapsulated Islet Allografts

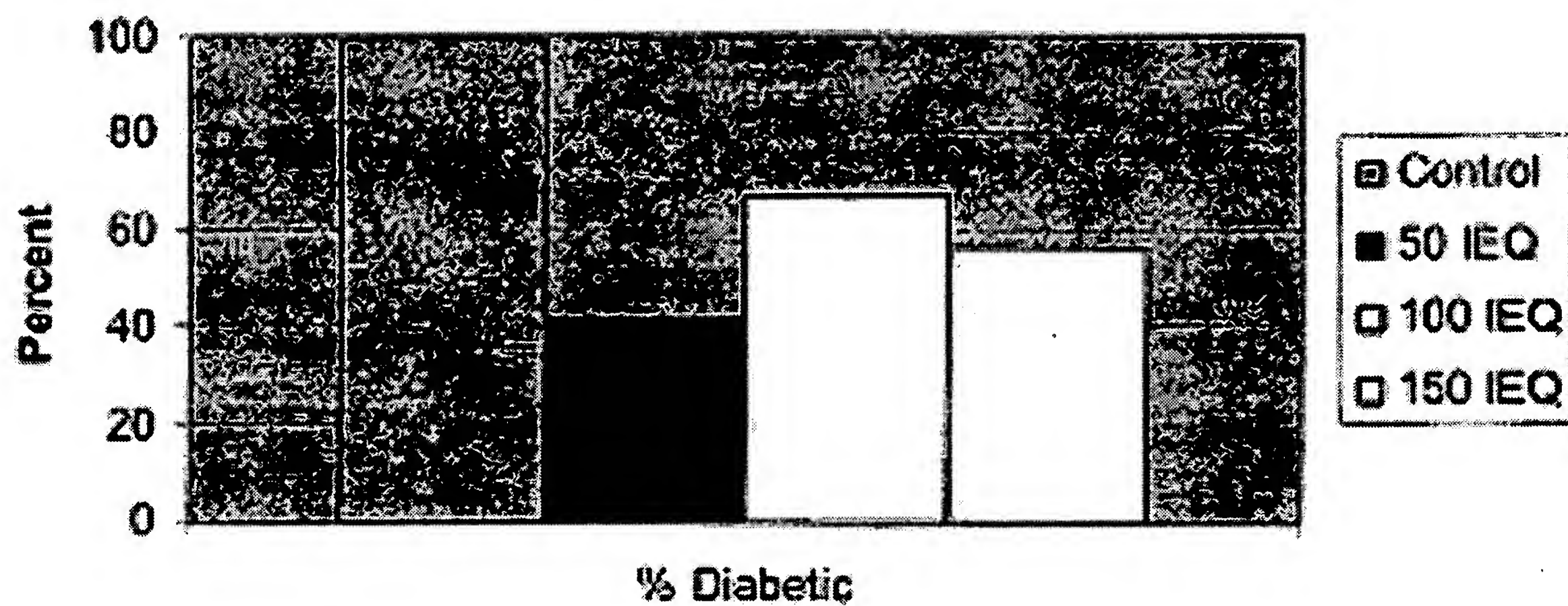


Exhibit 2

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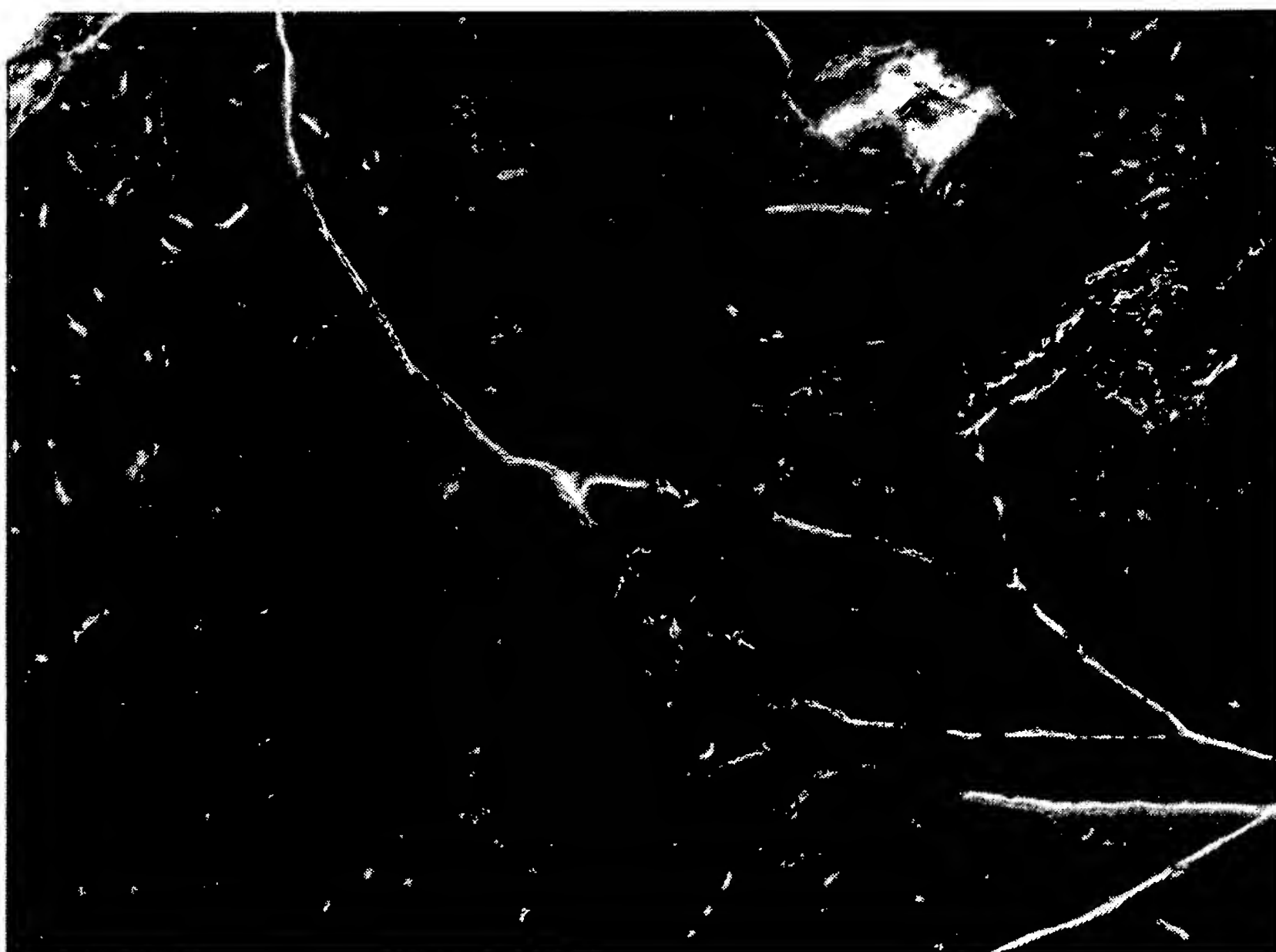


Exhibit 3

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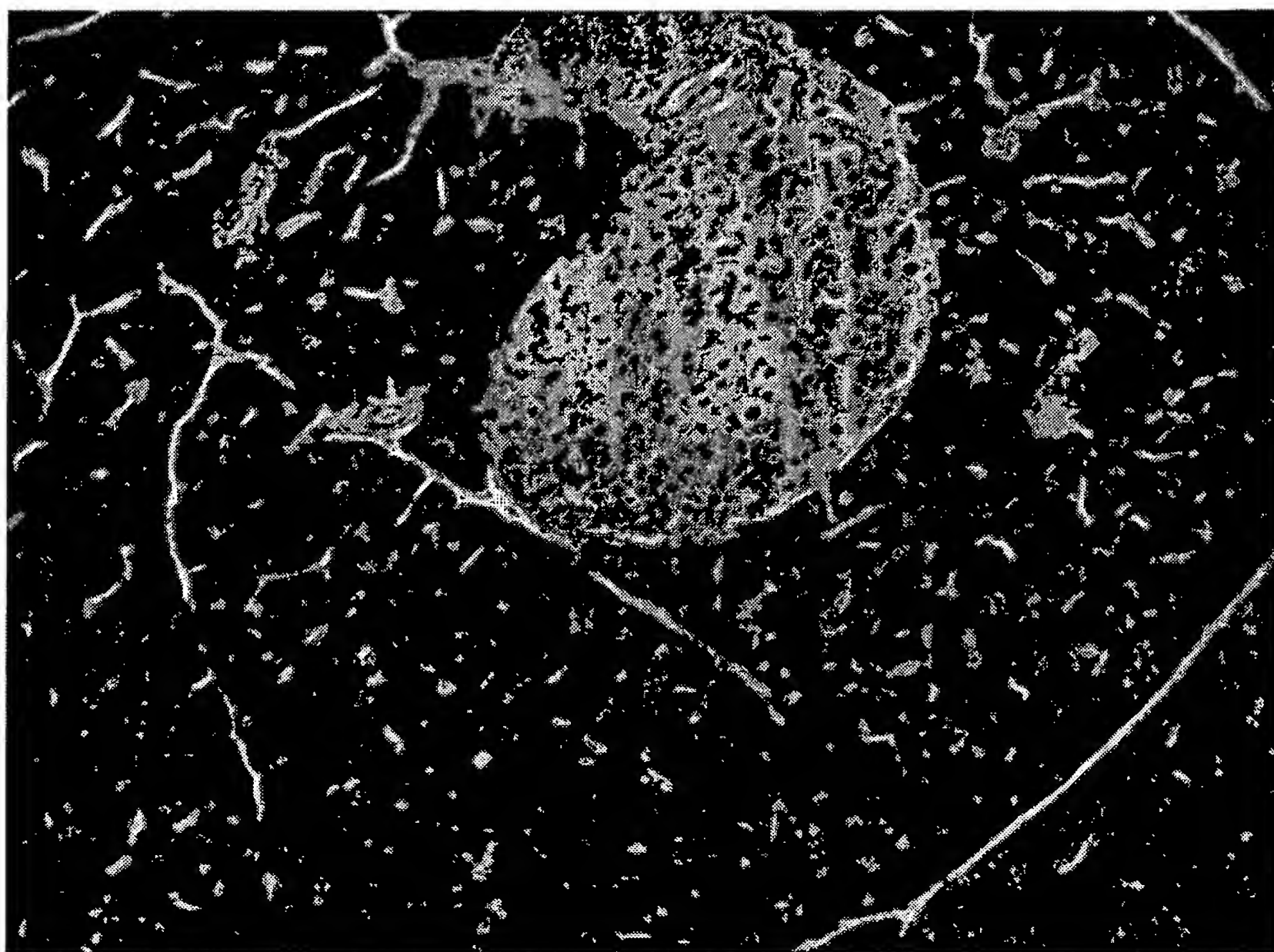


Exhibit 4



Exhibit 5

Exhibit A

CURRICULUM VITAE

David William Scharp, M.D.

Born: July 5, 1945
Washington, Illinois

Social Security Number: 327-36-7524

Marital Status: Wife: Jeanette

Children: Kevin Scharp
Daniel Scharp
Anna Scharp
David Bondurant
Melissa Bondurant

Pre-Medical Education: University of Missouri
Columbia, Missouri
1963-1966

Medical Education: Washington University School of Medicine
St. Louis, Missouri
1966-1970

Graduate Hospital Experience:

Intern in Surgery
7/1/70-6/30/71
Barnes Hospital/Washington University

Surgical Resident
7/1/71-6/30/72 & 7/1/74-6/30/76
Barnes Hospital/Washington University

Surgical Research Fellow
7/1/72-6/30/74
Washington University - Department of Surgery

Academic Positions:

Assistant Professor of Surgery
1976-1983
Washington University School of Medicine

Associate Professor of Surgery
1983-1991
Washington University School of Medicine

Professor of Surgery
1991-President
Washington University School of Medicine

Leave of Absence
1/1/94-7/1/95

Commercial Positions:

Novocell, Inc.
Chief Scientific Officer

Neocrin Company
Chief Scientific Officer 1/1/94-7/31/99
Executive Vice President of Medical Affairs 1/1/94-7/31/99
Executive Vice President for Research 1/1/94-11/1/95
Executive Vice President, Research and Development 11/1/95-President

McDonnell Douglas Corporation 1984-1987
Contractual Research Investigator
Electrophoretic Separation of Islet Cells

Cytotherapeutics, Inc. 1989-1993
Founding Scientist
Scientific Advisory Board Member
Contractual Research Investigator

Patents:

“Islet Isolation Process”

DE191613T – 1987

DE3650662D – 1998

EP0191613 – 1986

EP0191613 – 1989

EP0191613 – 1997

JP61183226 – 1986

US4868121 – 1989

US5322790 – 1994

“Method to Isolate Clusters of Cell Sub-Types from Organs”

AU1934988 – 1989

CA1340406 – 1999

EP0382727 – 1990

EP0382727 – 1991

JP2504222T – 1990

US5079160 – 1992

WO8809667 – 1988

“Implantable Biocompatible Immunoisulatory Vehicle for Delivery of Selected Therapeutic Products”

AT156344T – 1997

AU666118 – 1996

AU682796 – 1997

AU2004192 – 1992

AU3902095 – 1996

CA2109085 – 1992

CA2109085 – 2003

DE69221484D – 1997

DE69221484T – 1998

DK585368T – 1998

EP0585368 – 1994

EP0585368 – 1994

EP0585368 – 1997

ES2107537T – 1997

FI934545 – 1993

FI934545D – 1993

GR3025301T – 1998

HK1001832 – 1998

JP6507412T – 1994

NO308198B – 2000

NO933842 – 1993

SG47470 – 1998

US5798113 – 1998
US5800828 – 1998
US5871767 – 1999
US6083523 – 2000
US6322804 – 2001
US2002150603 – 2002
WO9219195 – 1992

“Methods for Coextruding Immunoisulatory Implantable Vehicles with a Biocompatible Jacket and a Biocompatible Matrix Core”

US5800829 – 1998

“Methods for Treating Diabetes by Delivering Insulin from Biocompatible Cell Containing Devices”

US5869077 – 1999

“Methods for Making Immunoisulatory Implantable Vehicles with a Biocompatible Jacket and a Biocompatible Matrix Core”

US5834001 – 1998

US5874099 – 1999

“Use of Pouch for Implantation of Living Cells”

AU4788993 – 1994

CA2140905 – 1994

EP0655910 – 1995

EP0655910 – 1996

JP8500033T – 1996

US5916554 – 1999

WO9403154 – 1994

Hospital Appointments:

Assistant Surgeon 1976-1983

Associate Surgeon - 1983-Present

Barnes Hospital, St. Louis, Missouri

Attending Surgeon 1982-1985

Consulting Surgeon 1976-1982

Associate Chief of Surgery 12/86-9/90

Veterans Administration Medical Center, St. Louis, Missouri

Consulting Surgeon 1985-7/95
Acting Chief of Surgery 3/86-12/86
St. Louis Regional Hospital, St. Louis, Missouri

Consulting Surgeon 1976-1985
St. Louis Children's Hospital, St. Louis, Missouri

Consulting Surgeon 1976-1985
Chief of Surgery 1981-1982
St. Louis County Hospital, St. Louis, Missouri

Attending Surgeon 1976-1982
St. Louis City Hospital, St. Louis, Missouri

Licensure: Missouri 1970

Certification: American Board of Surgery 1979
Fellow American College of Surgery 1982
Recertification: American Board of Surgery 1989

Medical Societies:

American College of Surgeons
American Diabetes Association
American Federation of Clinical Research
American Pancreatic Association
American Society for Artificial Internal Organs
American Surgical Association
Association for Academic Surgery
Society of University Surgeons
Tissue Culture Association
American Society of Transplant Surgeons
The Cell Transplantation Society
United Network of Organ Sharing - Region 8
International Pancreas & Islet Transplantation Association

Honors and Awards:

St. Louis Surgical Society Award for Research
Recipient 1973 & 1974
NIH Research Career Development Award
Recipient 1977-1982
NIH NAIMMDD Site Visit Teams
Member 1980-1995

NIH Surgery, Anesthesiology, and Trauma Study Section

Member 1985-1989

Reserve Member Status 1989-1995

World Journal of Surgery

Guest Editor - Islet Transplantation Symposium 1984

“Separation of Islet Cells in Microgravity by Continuous-Flow Electrophoresis”, NASA -
McDonnell Douglas Astronautics Corp. - STS-8, Space Shuttle, “Challenger”,
Experiment 1984

Editorial Reviewer:

Diabetes, Surgery, Journal Clinical Investigation

Grant Reviewer

Canadian Diabetes Association

Medical Research Council of Canada

National Surgical Advisor - Digestive Disease Center of Excellence -
The Humana Corporation 1986-1994

Alpha Omega Alpha - Washington University Chapter - Elected
Faculty Member January 1988

Outstanding Profession/Scientific Employee - Federal Employee of the Year Award
Program - St. Louis Federal Executive Board 1990

The Huddinge Hospital Transplant Lectureship - Annual Meeting of the Swedish Society for
Medical Science, Stockholm, Sweden, December 1990

Council Member - Cell Transplantation Society 1992-Present

Council Member - International Pancreas & Islet Transplantation Association 1993-Present

Editorial Board

Cell Transplantation 1992-1993

Transplantation Science

Committee Appointments:

Washington University Animal Studies Committee

Chairman 1991-1994

Washington University Medical Center Alumni Association

Committee Member 1991-1994

International Juvenile Diabetes Research Foundation Medical Science Review Committee
1990-1993

UNOS Pancreas Subcommittee Member 1991-1995

American Society of Transplant Surgeons Program and Publications Committee 1989-1991

Academic Freedom and Tenure Hearing Committee

Member 1985-1991

Washington University Committee on the Humane Care of Laboratory Animal Member
Member 1984-1990

Operating Room Technician Program
 Forest Park Community College
 Advisory Committee 1976-1995
 Chairman 1986-1995
 Mid-America Transplant Association
 Member Professional Advisory Board 1985-1995
 American Cancer Society Institutional Research Grants
 Washington University Committee for Cancer Research
 Member 1979-1989
 Chairman 1982-1989
 "Health Views" - Editorial Advisory Board
 Member 1984-1988
 American Diabetes Association, St. Louis Chapter
 Research Committee 1985-1988
 Department of Surgery Animal Facility
 Director 1980-1984
 Washington University Faculty Senate
 Member 1981-1983
 Executive Committee of the Faculty Council
 Member 1982-1984
 Clinical Sciences Research Building Animal Surgery Suite
 Director 1984-1985
 Department of Engineering Master Degree Thesis Review Committee:
 1979-John Bergen - "Kinetics of Insulin Secretion from Pancreatic Islets of Langerhans
 and Development of Islet Transplantation Chambers"
 1980-Paul Aegerter - "Microencapsulation of Living Cells to Prevent Immunological
 Response"
 1983-Shiow Meei Lin - "Testing of a Mathematical Model for Islet Transplantation
 Chambers"
 1987-Donna Wilkinson - "Coating of Live Cells with Polysaccharide Derivatives"
 1989-Mary Blanchard - "Quantification of Low Concentrations of Polysaccharide
 Derivatives and Their Effect on Cell Viability"
 1990-Ph.D. Thesis Review, Donna Hawk-Reinhard - "Purification of Pancreatic Islets of
 Langerhans Using Cell Electrophoresis"
 St. Louis VAMC Committees
 Comprehensive Planning Committee
 Chairman 1988-1990
 Administrative Executive Board 1988-1990
 Professional Standards Board 1988-1990
 Research Committee 1988-1994
 District Planning Board 1988-1990

Barnes Hospital Committees

Chaplaincy Committee 1992-1994

Emergency Room Committee 1978-1984

Search Committee for ER Director 1978-1984

Patient Education Parent Committee 1979

Surgery Patient Education Subcommittee Chairman 1981-1988

Tissue Culture Association

Publicity Chairman 1980

Invited Presentations, Selected:

The Kroc Foundation

Islet Transplantation Workshop 1974

Islet Transplantation Workshop 1979

Islet Transplantation Workshop 1982

National Institutes of Health

National Conference on Diabetes 1979

National Conference on Diabetes 1983

Juvenile Diabetes Foundation

Conference on Research Tissue 1981

National Meeting, Keynote Speaker 1984

International Scientific Research Conference 1985

German Diabetes Association, Giessen, West Germany

Islet Transplantation Workshop 1980

Islet Transplantation Workshop 1989

American Society of Artificial Organs

Annual Meeting - Keynote Speaker 1983

Session Co-Chairman 1987

International Symposium on Organ Transplantation in Diabetes

The Hague, Netherlands 1983

International Symposium on Kidney and Pancreas Transplantation

Perugia, Italy 1984

International Islet Transplantation Workshop

Canberra, Australia 1984

XII Congress of the International Diabetes Federation

Madrid, Spain 1985

XIII Congress of the International Diabetes Federation

Sydney, Australia 1989

National Disease Research Interchange

Human Tissue Conference 1985

Human Tissue Conference 1986

Human Tissue Conference 1987

Human Tissue Conference 1990

National Disease Research Interchange - Chairman of Task Force on "Biohazard and Contamination in the Use of Human Tissue and Organs"
Philadelphia, PA 1988

American Diabetes Association National Meeting - Session Co-Chairman for "Forms of Therapy" 1986

Visiting Scientist Program - University of Kansas Diabetes Center
Kansas City, Kansas 1986

Immunology of Diabetes Symposium - Member of International Advisory Committee
Edmonton, Canada 1986

International Symposium on Complications of Diabetes
The Hague, Netherlands 1986

Visiting Professorship - Department of Surgery - University of Minnesota
Minneapolis, Minnesota 1986

May 8th Endocrine Days
Victoria, British Columbia 1987

Second Annual Visiting Professorship in Diabetes - University of Wisconsin
Madison, Wisconsin 1987

First International Course on Transplantation
Venice, Italy 1987

Progress in Organ Transplants, Tissue Replacements and Implants
Sponsored by Biomedical Business International, New York 1987

Josiah Brown Memorial Symposium on Pancreas Beta Cell Transplantation
Los Angeles, California 1987

Seventh Workshop of the AIDSPIT Study Group
Igls, Austria 1988

First international Congress on Pancreatic and Islet Transplantation
Stockholm, Sweden 1987

Thirty-Fourth Annual Meeting of ASAIO, Invited Speaker "Modern Treatment of Insulin Dependent Diabetes"
Reno, Nevada 1988

Sixth Gordon Research Conference on Drug Carriers in Biology and Medicine
Plymouth, New Hampshire 1988

XII International Congress of the Transplantation Society
Sydney, Australia 1988

Second International Congress on Pancreatic and Islet Transplantation
Minneapolis, Minnesota 1989

Biology of Tissue Transplantation Symposium
Bethesda, Maryland 1989

Ninth Workshop of the AIDSPIT Study Group
Igls, Austria 1990

Society for Surgery of the Alimentary Tract Postgraduate Course, "Medical Aspects of Transplantation of the Liver, Pancreas and Intestine"
San Antonio, Texas 1990

Moderator for Pancreas Transplantation Scientific Session - American Society of Transplant Surgeons

Chicago 1990

UCLA Symposium on Molecular & Cellular Biology, "Tissue Engineering"

Keystone, Colorado 1990

The Huddinge Hospital Transplant Lectureship Annual Meeting of the Swedish Society for Medical Science

Stockholm, Sweden 1990

Third International Congress on Pancreatic and Islet Transplantation - Moderator and Plenary Speaker

Lyon, France 1991

European Association for the Study of Diabetes - Plenary Speaker

Dublin, Ireland 1991

Visiting Professor - University of Wisconsin

Madison, Wisconsin 1991

Moderator for Clinical Transplantation-Pancreas and Islets - XVIth International Congress of the Transplantation Society

Paris 1992

American Diabetes Association 53rd Annual Meeting - Plenary Speaker

Las Vegas, Nevada 1993

Fourth International Congress of Pancreas and Islet Transplantation - Plenary Speaker

Amsterdam 1993

IVth Joint Meeting of the Lawson Wilkins Pediatric Endocrine Society and the European Society for Pediatric Endocrinology - Symposium Speaker

San Francisco 1993

American Association for Clinical Chemistry

New York 1993

Publications

Abstracts:

1. Ballinger, W.F., Lacy, P.E., Scharp, D.W., Kemp, C.B., Knight, M. - Isografts and allografts of pancreatic islets in rats. *Brit. J. Surg.* 60:313, 1973
2. Kemp, C.B., Knight, M.J., Scharp, D.W., Lacy, P.E., Ballinger, W.F. - Islets of Langerhans injected into the portal vein of the diabetic rat. *South African Journal of Surgery* 11:135, 1973
3. Kemp, C.B., Knight, M.J., Scharp, D.W., Lacy, P.E., Ballinger, W.F. - Proceedings: Implantation of pancreatic islets into the portal vein of diabetic rats. *Brit. J. Surg.* 60:907, 1973
4. Scharp, D.W., Kemp, C.B., Knight, M.J., Murphy, J., Newton, W., Ballinger, W.F., Lacy, P.E. - Long term results of portal vein islet isografts and allografts in the treatment of Streptozotocin induced diabetes. *Diabetes* 23:359, 1974
5. Scharp, D.W., White, D.J., Ballinger, W.F., Lacy, P.E. - Transplantation of intact islets of Langerhans after tissue culture. *In Vitro* 9:364, 1974
6. Knight, M.J., Scharp, D.W., Kemp, C.B., Nunnolley, S.B., Ballinger, W.F., Lacy, P.E. - Cryopreservation of pancreatic islets. *European Surgical Research* 6(1):89, 1974
7. Ballinger, W.F., Murphy, J.J., Scharp, D.W., Hirshberg, G.E., Karl, R.C., Lacy, P.E. - Isolation and preservation of human islets of Langerhans for transplantation in the treatment of diabetes. *European Society for Exp. Surg., Tenth Congress* 1975
8. Griffith, R.C., Scharp, D.W., Ballinger, W.F., Lacy, P.E. - A morphologic study of intrahepatic portal vein islet isografts. *Diabetes* 34(2):419, 1975
9. Dodi, G., Scharp, D., Feldman, S., Maresca, B., Ballinger, W., Lacy, P. - Treatment of exocrine pancreatic dysfunction in diabetic rats by islet transplantation. *European Surgical Research* 9(1):98, 1977
10. Scharp, D.W., Merrell, R.C., Feldman, S., Ruwe, E., Feldmeier, M., Ballinger, W., Lacy, P. - Long term culture of islets of Langerhans utilizing a rotational culture method. *In Vitro* 13:174, 1977
11. Scharp, D., Krupin, T., Waltman, S., Oestrich, C., Feldman, S., Ballinger, W., Becker, B. - Relationship of abnormal insulin release to fluorophotometry in experimental diabetes. *Diabetes* 27(2):435, 1978

12. Scharp, D.W., Merrell, R.C., Feldmeier, M.M., Downing, R., Ballinger, W.F. - Pseudo-islet formation and culture from canine isolated pancreatic cells. *In Vitro* 15:216, 1979
13. Rajotte, R.V., Scharp, D.W., Downing, R. Molnar, G.D., Ballinger, W.F. - The transplantation of frozen-thawed rat islets transported between centers. *Diabetes* 28:377, 1979
14. Downing, R. Scharp, D.W., Grieder, M., Ballinger, W.F. - Mass isolation of islets of Langerhans from the dog pancreas. *Diabetes* 28:426, 1979
15. Feldman, S.D., Scharp, D.W., Lacy, P.E., Ballinger, W.F. - Fetal pancreas isografts, cultured and uncultured to reverse Streptozotocin induced diabetes mellitus. *The Association for Academic Surgery* 12:116, 1979
16. Grieder, M.H., DeSchryver-Kecskemeti, K. Gingerich, R.L., Scharp, D.W. - In vitro studies using canine pseudo-islets and rat antrum cultures as models. *UCLA Symposium*, December 3, 1979
17. Scharp, D.W., Feldmeier, M.M., Rajotte, R.V., DeSchryver, K., Bell, M. - Human pseudo-islet formation, culture and preservation. *Diabetes* 29(2):18A, 1980
18. Gingerich, R.L., Scharp, D.W., Grieder, M.H., Dye, E.S., Mousel, K.A. - A new in vitro model to study secretion and biochemistry of pancreatic polypeptide (PP). *Diabetes* 29(2):30A, 1980
19. Bergen, J.F., Mason, N.S., Scharp, D.W., Sparks, R.E. - Insulin inhibition of islets in transplantation chambers. Presented at International Society for Artificial Organs Meetings, Paris, July 8-10, 1981
20. Sparks, R.E., Mason, N.S., Finley, T.C., Scharp, D.W. - Development, testing and modeling of an islet transplantation chamber, *ASAIO Meetings*, Chicago, April, 1982
21. Long, J.A., Adair, W.S., Scharp, D.W. - Hybridoma production against pancreatic cells. *Diabetes* 31(2):20A, 1982
22. Scharp, D.W., Hirshberg, G., Long, J.A. - The effect of islet dosage and time on rat portal vein isografts. *Diabetes* 31(2):162A, 1982
23. Scharp, D.W., Lacy, P.E. - The isolation and alteration of islet tissue for transplantation. *The Tissue Culture Association Meeting*, San Diego, June, 1982. *In Vitro Suppl.* 1, 1982
24. Long, J.A., Adair, W.S., Scharp, D.W. - An immunological approach to islet cell purification. *J. Cell Biol.* 95:4061, 1982

25. Sparks, R.E. Mason, N.S., Finley, T.C., Scharp, D.W. - Design of islet transplantation chambers giving a normal glucose tolerance test. ISAO Meetings, Kyoto, Japan, November, 1983
26. Sparks, R.E., Mason, N.E., Finley, T.C., Scharp, D.W. - Islet transplantation chamber models - assumption for insulin generation and glucose diffusion. International Symposium on Organ Transplantation in Diabetes, The Netherlands, September, 1983
27. Sparks, R.E., Mason, N.S., Scharp, D.W. - Some present directions in research on tissue transplantation chambers. International Conference on Artificial Organs, Glasgow, Scotland, September, 1983
28. Sparks, R.E., Mason, N.S., Finley, T.C., Scharp, D.W. - "A distributed source-model for hybrid artificial pancreas", presented by ASAIO, Toronto, Ontario, Canada, April, 1983
29. Scharp, D.W., Feldmeier, M.M., Olack, B.J., Swanson, C.J., O'Shaughnessey, S.F. - Electrophoretic purification of islet cells for transplantation. Diabetes 33(1):179A, 1984
30. Scharp, D.W., Rajotte, R.V., Kneteman, N.M., Lacy P.E. - Zero gravity electrophoresis of islet cells. 10th International Congress of the Transplantation Society Meeting, Minneapolis, August, 1984
31. Scharp, D.W., Lacy, P.E. - Human islet isolation and transplantation. Diabetes 34(1):5A, 1985
32. Kneteman, N.M., Alderson, D., Scharp, D.W. - Canine pancreatic islet allotransplantation: dose adjusted cyclosporine A vs azathioprine - steroid, Diabetes 34(1):62A, 1986
33. Alderson, D., Kneteman, N.M., Scharp, D.W. - The isolation of purified human islets of Langerhans. Diabetes 34(1):81A, 1986
34. Corlett, M.P., Fonseca, P., Scharp, D.W. - Detrimental effect of warm ischemia on islet isolation in rats and dogs with protection by oxygen free radical scavengers. Diabetes 36(1):223A, 1987
35. Scharp, D.W., Lacy, P.E., Finke, E.H., Olack, B.J. - Seven day culture of Ficoll purified human islets. Diabetes 36(1):222A, 1987
36. Corlett, M.P., Scharp, D.W. - Effect of warm ischemia on islet isolation in rats and dogs. The Association for Academic Surgery, Orlando, Florida, November 1-4, 1987
37. Misler, S., Gee, W., Scharp, D., Manchester, J., Falke, L. - Metabolically regulated potassium channels in human islet cells. Diabetes 37(1):6A, 1988

38. Atkinson, M.A., Maclaren, N.K., Riley, W.J., Scharp, D.W., and Holmes, L. - M_r 64,000 autoantibodies (64KA) predict insulin dependent diabetes (IDD). *Diabetes* 37(1):98A, 1988
39. Scharp, D.W., Lacy P.E., Ricordi, C., Boyle, P., Santiago, J.V., Gingerich, R.L., Anderson, C.B., Flye, M.W. - Human islet transplantation in patients with Type I diabetes. Presented at XII International Congress of the Transplantation Society, Sydney, Australia, August 14-19, 1988
40. Riley, W.J., Maclaren, N.K., Atkinson, M.A., Scharp, D.W., Lacy, P.E. - Islet autoantibodies in "prediabetes". Ninth International Workshop on the Immunology of Diabetes, Satellite Symposium on Beta Cell Destruction and Restoration in Type I Diabetes. November 27-29, Sydney, Australia, 1988
41. Atkinson, M.A., Maclaren, N.K., Riley, W.J., Scharp, D.W., Holmes, L. - The natural history and predictive value of M_r 64,000 islet cell antigen. Ninth International Workshop on the Immunology of Diabetes, Satellite Symposium of the International Diabetes Federation, Melbourne, Australia, 1988
42. Scharp, D.W., Chern, H.T., McCullough, C.S., Gingerich, R.L. - Lack of glucose induced insulin responsiveness in canine islets. 49th Annual Meeting of the American Diabetes Association, Detroit, Michigan, June 3-6, 1991. *Diabetes* 38(1):209A, 1989
43. Chern, H.T., Scharp, D.W., McCullough, C.S. - Cryogenic storage of purified canine islets. 49th Annual Meeting of the American Diabetes Association, Detroit, Michigan, June 3-6, 1989. *Diabetes* 38(1):246A, 1989
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